**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF MICHIGAN**

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| LISA KOSTO, MELISSA THOMPSON, MARGARET MASSIE, DEBBIE ANDREWS, KAYLANN RYAN, and REBECCA QUARANTA, individually and on behalf of all others similarly situated, | ) | |
| Plaintiffs, | ) | No. |
| v. | ) | JURY TRIAL DEMANDED |
| ALLERGAN INC., F/K/A INAMED CORPORATION; ALLERGAN USA, INC.; and ALLERGAN PLC, | ) | |
| Defendants. | ) | |

**CLASS ACTION COMPLAINT**

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Plaintiffs Lisa Kosto, Melissa Thompson, Margaret Massie, Debbie Andrews, Kaylann Ryan, and Rebecca Quaranta ("Plaintiffs"), on behalf of themselves and all others similarly situated, by and through counsel and pursuant to the Federal Rules of Civil Procedure, brings this Class Action Complaint against Defendants Allergan Inc., f/k/a Inamed Corporation, Allergan USA, Inc., and Allergan plc ("Defendants" or "Allergan") and allege as follows:

## INTRODUCTION

1. Allergan manufactures and sells BIOCELL saline-filled and silicone-filled breast implants and tissue expanders. BIOCELL products have a textured surface, or shell, which was intended to reduce complications post implantation. Instead, these products subject patients to a significantly increased risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system.

2. On July 24, 2019, the FDA issued a Class I Recall notice for Allergan's BIOCELL products[1] ("Recalled BIOCELL Implants") after concluding that the vast

[1] The Recalled BIOCELL Implants include: (1) **Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant)** approved under P990074. The following are the textured styles: Style 163, BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants; Style 168, BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile); Style 363, BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection; Style 468, BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants; (2) **Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants)** approved under P020056. The following are the textured styles: Style 110, BIOCELL Textured Round Moderate Projection Gel

majority of BIA-ALCL cases occurred in patients who had implanted Recalled BIOCELL Implants. A Class I Recall is defined as "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."

3. In its Safety Communication, the FDA announced that more than 80% of the BIA-ALCL cases reported worldwide occurred in patients who had Recalled BIOCELL Implants implanted at the time of diagnosis. Moreover, "12 of the 13 patients for which the manufacturer of the implant is known [were] confirmed to have an Allergan breast implant."

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Filled Breast Implants; Style 115, BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants; Style 120, BIOCELL Textured Round High Projection Gel Filled Breast Implants; Style TRL, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRLP, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRM, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRF, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRX, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TCL, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCLP, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCM, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCF, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCX, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TSL, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSLP, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSM, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSF, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSX, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; (3) **Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants** approved under P040046. The following are the textured styles: Style 410FM; Style 410FF; Style 410MM; Style 410 MF; Style 410 FL; Style 410 ML; Style 410 LL; Style 410 LM; Style 410 LF; Style 410 FX; Style 410 MX; Style 410 LX; (4) **Allergan tissue expanders** originally cleared as: Natrelle 133 Plus Tissue Expander (K143354); Natrelle 133 Tissue Expander with Suture Tabs (K102806);

4. The FDA further stated that its "analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers." It concluded that continued distribution of the Recalled BIOCELL Implants "would likely cause serious, adverse health consequences and potentially death from BIA-ALCL."

5. Allergan, complying with the FDA's request, issued a worldwide recall for the Recalled BIOCELL Implants that same day.

6. As is clear from its post-recall conduct and representations, Allergan has failed to—and has no plans to—provide medical monitoring for Plaintiffs and the class members due to the increased risk of developing BIA-ALCL from the Recalled BIOCELL Implants.

7. In a July 30, 2019 letter to "Allergan Plastic Surgery Customer[s]", Carrie Strom, Allergan's Senior Vice President, U.S. Medical Aesthetics, announced a new "BIOCELL Replacement Warranty" for patients "currently implanted" with Recalled BIOCELL Implants. Under the "warranty," which extends until July 24, 2021, implanted patients who choose to undergo a revision surgery will receive Allergan smooth implants from Allergan at no cost. Allergan will not, however, pay any other associated fees, including surgical costs.

8. According to the letter, patients who choose to keep their Recalled BIOCELL Implants (and therefore are at a significantly increased risk of developing

BIA-ALCL) may be eligible for reimbursement for certain diagnostic and surgical fees, but that dollar figure is capped.

9. BIA-ALCL is a serious cancer that can metastasize and prove fatal. The diagnostic process can be invasive. Treatment includes removal of the implants and may also require chemotherapy and radiation.

10. Now that these products have been recalled, Allergan refuses to appropriately care for, monitor, and compensate Plaintiffs and the class members. Plaintiffs and the class members will be forced to expend significant monies for removal of the recalled implants, surgical and diagnostic fees, medical monitoring, and the invasive diagnostic procedures necessitated by the increased risk to which Defendants have knowingly exposed Plaintiffs and the class members.

11. For decades, Allergan knew that its Recalled BIOCELL Implants cause BIA-ALCL. Nonetheless, it sold and benefitted from the sale of these products, at Plaintiffs' and the class members' expense.

12. Defendant sold the products with complete disregard and reckless indifference to the safety of Plaintiffs and members of the Nationwide Class defined as: "All persons in the United States who, for personal use, implanted Allergan's BIOCELL products that have been recalled by the FDA and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma."

13. Accordingly, Plaintiffs seek equitable relief for themselves and the Medical Monitoring Class in the form of medical monitoring as a result of their implantation of, and exposure to, the Recalled BIOCELL Implants, which are causing them to be at increased risk for developing breast implant-associated anaplastic large cell lymphoma. Plaintiffs also seek all costs associated with explantation of the Recalled BIOCELL Implants.

## THE PARTIES

### A. Plaintiffs

14. Plaintiff Lisa Kosto is and was a resident and citizen of the State of Michigan and the United States at all times relevant to this action. On or about November 2004, Plaintiff received Natrelle Saline-Filled Breast Implants Style 468 (P990074), which are on the list of Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

15. Plaintiff Melissa Thompson is and was a resident and citizen of the State of Connecticut and the United States at all times relevant to this action. On

October 26, 2015, Plaintiff received the Natrelle 133 Tissue Expanders with Suture Tabs (K102806), which are on the list of Recalled BIOCELL Implants. As a direct and proximate result of having the tissue expanders implanted (which were removed on June 20, 2016), Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had these expanders had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

16. Plaintiff Margaret Massie is and was a resident and citizen of the State of Washington and the United States at all times relevant to this action. In mid-2007, Plaintiff received Style 363 of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

17. Plaintiff Debbie Andrews is and was a resident and citizen of the State of Texas and the United States at all times relevant to this action. In 1995, Plaintiff

received Style 168, then known as McGhan RTV Saline-Filled Mammary Implant (P990074), which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

18. Plaintiff Kaylann Ryan is and was a resident and citizen of the State of Texas and the United States at all times relevant to this action. In 2016, Plaintiff received Style TRM, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants (P020056), which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

19. Plaintiff Rebecca Quaranta is and was a resident and citizen of the State of Florida and the United States at all times relevant to this action. In 2017, Plaintiff received Style 410 MF Natrelle Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants (P040046), which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

**B. Defendants**

20. Defendant Allergan plc is a publicly traded corporation headquartered in Dublin, Ireland. Its administrative headquarters for the United States are in Bridgewater Township, New Jersey.

21. Allergan, Inc., a wholly-owned subsidiary of Allergan plc, is incorporated under the laws of Delaware with a principal place of business in Bridgewater Township, New Jersey.

22. Defendant Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

23. Defendants Allergan plc; Allergan, Inc.; and Allergan USA, Inc. are collectively referred to as "Defendants" or "Allergan."

24. Allergan entered the breast implant market through California-based McGhan Medical Corporation ("McGhan"), its predecessor corporation. BIOCELL textured implants were originally developed in the 1980s and early 1990s by McGhan.

25. McGhan was a leading manufacturer of silicone products for plastic and reconstructive surgery. In 1985 it became a subsidiary of First American Corporation, a publicly held company. In 1986, First American changed its name to Inamed Corporation.

26. In March 2006, Allergan acquired Inamed and its wholly-owned subsidiary, McGhan, as well as the BIOCELL trademark. In doing so, it assumed the liability for its past and present manufacturing of breast implant products. At the time, Inamed was one of the largest implant makers in the world and one of the two largest manufacturers in the United States.

27. In 2015, Actavis, a pharmaceutical company headquartered in Dublin, Ireland with a principal place of business in New Jersey, purchased Allergan and adopted the Allergan plc name.

28. Allergan's Medical Aesthetics division, which is responsible for its BIOCELL breast implants and tissue expanders, is overseeing the recall, and is administering Allergan's inadequate Replacement "Warranty."

29. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, Defendants carried out a joint scheme, business plan, or policy in all respects pertinent hereto, and the acts of each Defendant are legally attributable to the other Defendant(s).

## JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interest and costs; (c) at least one Plaintiffs and is a citizen of a different state than at least one Defendant; and (c) members of the class, including Plaintiff, are citizens of a state and at least one of the Defendants is a citizen or subject of a foreign state.

31. The Court has personal jurisdiction over the Defendants because they have sufficient minimum contacts in this District to render the exercise of jurisdiction by this Court proper and fair.

32. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and (c)(2) because a substantial part of the acts giving rise to Plaintiffs' claims occurred in this District and because Defendants are subject to personal jurisdiction within this District.

## FACTUAL ALLEGATIONS

### A. A Relevant History of Breast Implants and Tissue Expanders

33. Breast implants are medical devices that are implanted under the breast tissues to increase breast size, replace breast tissue that has been removed due to cancer, surgery, or other trauma, or to correct developmental defects. Tissue expanders are a type of inflatable breast implant, typically used in breast reconstruction surgeries, to stretch skin and muscle to create space for a more permanent implant.

34. The FDA has approved two types of implants for sale in the United States: saline (saltwater solution)-filled and silicone-gel filled. Both types of implants vary in size, shell thickness, gel viscosity, and shape, and have an outer shell made of either smooth or textured silicone.

35. Manufacturers use a variety of techniques to create their textured implants. Allergan's process, which it uses for its Recalled BIOCELL Implants, creates the textured surface by dipping a silicone capsule into salt crystals before it is dry. The surface is washed and cured, leaving behind a pitted surface with randomly-sized indentations.

36. Every year approximately 400,000 women in the United States receive breast implants for augmentation or reconstruction, and breast augmentation is the most common cosmetic surgery in the country.

37. Breast implants were first introduced in the United States in the 1960s. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), granting the FDA the authority to review and approve new medical devices, including breast implants.

38. The FDA classifies medical devices depending on the risks associated with the device and the degree of regulation it deems appropriate. Its three-tiered system includes Class I devices (low to moderate risk to the user), Class II devices (moderate to high risk to the user), and Class III devices (high risk to the user). Following enactment of the MDA, the FDA classified breast implants as Class II devices. This classification did not require manufacturers to conduct any formal testing of the product; rather, they needed only to provide "reasonable assurance" that their devices would not harm patients. 21 U.S.C. § 360e(d)(2).

39. In 1988, in response to growing safety concerns, including reports of gel bleed and capsular contracture and studies warning of the link between silicone implants and cancer, the FDA re-classified both saline- and silicone-filled breast implants as Class III devices. In April 1991, following publication of the new regulations, the FDA began requiring breast implant manufacturers to obtain specific premarket approval ("PMA") by the FDA.

40. Tissue expanders, which are most often used for breast reconstruction, are inflatable breast implants that are slowly filled with saline over a period of time until the implant reaches the desired size. After the expansion is complete, the patient receives a permanent implant. Allergan's recalled tissue expanders did not go through the PMA process; rather, they were "cleared" through the FDA's 510k process, discussed *infra.*

**B. Allergan's BIOCELL Breast Implants**

**1. The PMA Process and Manufacturer Responsibilities**

41. Class III devices are those which the FDA has determined pose the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public. Through its PMA process, the FDA evaluates the safety and efficacy of Class III medical devices.

42. A PMA application must contain certain information that is critical to the FDA's evaluation of the safety and efficacy of the device at issue. A PMA and/or PMA Supplement application must include:

a. Proposed indications for use;

b. Description of the device, including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk);

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and efficacy of the device that is known or should reasonably be known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

43. Following PMA approval, the FDA requires labeling that sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing. The definition of labeling extends to posters, tags,

pamphlets, circulars, booklets, brochures, instruction books, Directions for Use ("DFU"), and fillers.

44. In order to provide continued reasonable assurance of the safety and effectiveness of the device, following PMA approval the manufacturer is subjected to ongoing and continuous reporting obligations. *See, e.g.,* 21 CFR §§ 803.50 et seq.; 21 CFR §§ 814.80 et seq. For example, 21 CFR § 803.50 requires that a manufacturer report, "[n]o later than 30 calendar days after it receives or becomes aware of information, from any source, that reasonably suggests that a device" "[m]ay have caused or contributed to a death or serious injury" or "has malfunctioned and this device or a similar device… would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." The FDA may institute additional reporting requirements as it determines appropriate. 21 CFR § 814.82.

45. Information is "reasonably known" if it can be obtained by contacting "a user facility, importer or other initial reporter;" is information that is in the manufacturer's possession; or is information that "can be obtain[ed] by analysis, testing, or other evaluation of the device." 21 CFR § 803.50(b). A manufacturer is required to investigate each reported event and evaluate the cause.

46. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to any medical device, including BIOCELL breast implants, rests with the manufacturer.

47. At all relevant times, and pursuant to 21 C.F.R. § 740(a), a PMA applicant manufacturer may voluntarily withdraw its product to carry out its responsibility to protect the public health and well-being from products that present a risk of injury or gross deception.

**2. The Development of Allergan's BIOCELL Implants**

48. McGhan originally developed BIOCELL textured implants in the late 1980s and early 1990s.

49. Beginning in the early 1990s, and pursuant to the FDA's oversight and approval, McGhan conducted numerous clinical trials of its implants, including clinical trials involving its silicone implants in reconstruction patients (the Adjunct study) and in reconstruction and revision patients (the CORE study). Patient follow-up was to occur until five years post-implantation (Adjunct study) and ten years post-implantation (CORE study).

50. On May 10, 2000, the FDA approved McGhan's PMA for the McGhan RTV Saline-Filled Mammary Implant, now known as the Natrelle Saline Breast Implant, including BIOCELL Styles 163, 168, 363, and 468, which are subject to the July 24, 2019 recall.

51. As a condition of the Defendant's PMA, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Defendants were required to, *inter alia*,

a. conduct and provide reports on a 10-year post approval study;

b. conduct and provide reports on a retrieval study, which would evaluate explanted implants and the mode of failure;

c. report any "adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and… has not been addressed by the device's labeling or…. has been addressed by the device's labeling, but is occurring with unexpected severity or frequency";

d. report, whenever it receives or becomes aware of information, from any source, that "reasonably suggests" that a device "may have caused or contributed to a death or serious injury; or has malfunctioned and such device or similar device… would be likely to cause or contribute to a death or serious injury if malfunction would occur."[2]

[2] *See* PMA P990074 Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf/P990074A.pdf (last accessed November 7, 2019).

52. In 2002, McGhan, which had become Inamed, submitted to the FDA a PMA for the Inamed Silicone-Filled Breast Implant, now known as the Allergan Natrelle Silicone-Filled Breast Implant. The primary clinical data set underlying the PMA was the CORE study.

53. In November 2006 the FDA approved this device, including BIOCELL Styles 110, 115, 120, TRL, TRLP, TRM, TRF, TRX, TCL, TCLP, TCM, TCF, TCX, TSL, TSLP, TSM, TSF, and TSX which are subject to the July 24, 2019 recall.

54. In February 2013, the FDA approved Defendants' PMA for their Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, including BIOCELL Styles 410FM, 410FF, 410MM, 410MF, 410FL, 410ML, 410LL, 410LM, 410LF, 410FX, 410MX, and 410LX which are subject to the July 24, 2019 recall.

55. As conditions of the 2006 and 2013 approvals, the FDA required Defendants to conduct six post-approval studies to evaluate and characterize the long-term performance and safety of the devices.[3]

56. In its 2002, 2006, and 2013 PMA approval letters, the FDA stated that "[f]ailure to comply with any post-approval requirement constitutes a ground for

[3] *See* PMA P20056 Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056a.pdf (last accessed November 7, 2019); and PMA 040046 Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046a.pdf (last accessed November 7, 2019).

withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

### 3. Allergan's BIOCELL Tissue Expanders

57. BIOCELL tissue expanders are not approved through the PMA process; they are "cleared" through the Section 510k process. A 510(k) application is a premarket submission to the FDA in which the manufacturer demonstrates that the device to be marketed is substantially equivalent to a legally marketed device. 21 CFR § 807.92(a)(3).

58. The 510(k) process requires the manufacturer to demonstrate that the device is as safe and effect as, and substantially equivalent to, a predicate 510(k) device. It does not require an independent assessment of the safety or efficacy of the device.

59. On January 5, 2011, Defendants' Natrelle 133 Tissue Expander with Suture Tabs received 510(k) clearance from the FDA and was classified as a Class II device subject to special controls set forth in 21 CFR § 878.3600.[4] Its predicate device was the Natrelle Style 133 Series Tissue Expander Matrix, also known the McGhan Magna-Site Tissue Expander, which was initially cleared in 1986 and is also subject to the July 24, 2019 recall.

[4] *See* Clearance Letter for K102806, http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102806.pdf (last accessed November 7, 2019).

60. On August 20, 2015, Defendants' Natrelle 133 Plus Tissue Expander received 510(k) clearance from the FDA as an unclassified device.[5] Its predicate device was the Mentor CPX 4 Breast Tissue Expanders and Mentor CPX 4 with Suture Tabs Breast Tissue Expanders., which was initially cleared in 2001.

61. The FDA's 510(k) clearance for the Defendants' tissue expanders required Defendants to comply with the labeling and medical device reporting requirements of the FDCA. 21 CFR §§ 801, 803.

62. Throughout the remainder of this Complaint, unless stated otherwise, "implant" refers to both breast implants and tissue expanders.

**C. Breast Implant-Associated ALCL**

63. BIA-ALCL is not breast cancer. It is a type of non-Hodgkin's lymphoma—cancer of the immune system. BIA-ALCL is a serious cancer that typically occurs in the scar tissue and fluid near the breast implant. Left untreated, it spreads throughout the body and can become fatal.

64. The primary symptoms of BIA-ALCL are persistent swelling, enlargement, a lump, mass, or pain in the area of the breast implant, enlarged lymph nodes, and rash, redness, or hardening of the breast. Symptoms typically occur a year or more after surgery and may appear up to at least ten years post-implantation.

[5] *See* Clearance Letter for K143354, http://www.accessdata.fda.gov/cdrh_docs/pdf14/K143354.pdf (last accessed November 7, 2019).

65. Diagnostic procedures are invasive and can include ultrasound, computed tomography scans ("CT scan"), and/or magnetic resonance imaging ("MRI"), fluid sampling via fine needle aspiration, and biopsy. Treatment includes surgical removal of the implant and surrounding tissue. Some patients may also require radiation, chemotherapy, or both.

66. The first report of BIA-ALCL in the medical literature occurred in 1997, and additional reports followed.

67. In November 2008, the Journal of the American Medical Association ("JAMA") published a retrospective analysis of 11 cases of ALCL between 1994 and 2006. It concluded that there is an association between silicone breast implants and ALCL.

68. On January 26, 2011, the FDA released a Safety Communication, entitled "Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants." It reported that, "[b]ased on the published case studies and epidemiological research, the FDA believes there is a possible association between breast implants and ALCL."

69. The FDA further observed that "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell." Allergan's BIOCELL products have a textured outer shell.

70. In July 2014, the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHR") issued a Medical Device Alert "to further encourage healthcare professional to report cases of ALCL in women who have breast implants or who have had them removed."

71. In March 2015, an analysis identified 173 cases of ALCL. The French National Cancer Institute claimed that "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant."

72. On May 19, 2016, The World Health Organization ("WHO") designated BIA-ALCL as a T-cell lymphoma, separate from other categories of ALCL, that can develop following breast implants.

73. Shortly thereafter, the National Comprehensive Cancer Network ("NCCN") established evidence-based consensus guidelines for the diagnosis and treatment of BIA-ALCL.

74. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel as part of its "ongoing monitoring of the association between breast implants and anaplastic large cell lymphoma."

75. In May 2017, a global analysis of approximately forty governmental databases shoed 363 cases of BIA-ALCL, of which 258 were reported to the FDA.

76. Experts began to call for the ban of textured breast implants. By September 2017, the FDA reported that it had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including 9 deaths.

77. On March 21, 2018, the FDA updated its 2011 warning. It recognized the WHO's designation and stated that "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

78. On May 9, 2018, Australia's TGA reported 72 cases of ALCL in Australian patients. A January 2018 study in JAMA Oncology reported that the risk of developing BIA-ALCL in women with breast implants was 421.8x higher than in women without, "implying an attributable risk approaching 100%."

79. Although the risk of BIA-ALCL is generally believed to be 1/300,000, textured implants substantially increase that risk. The FDA recently announced that, according to recent studies, the risk of BIA-ALCL in women with textured implants ranges from 1/3,817 and 1/30,000. The American Society of Plastic Surgeons estimates the current risk of BIA-ALCL to be between 1/2,207 and 1/86,029 for women with textured implants. TGA reported the risk as 1/1,000 to 1/10,000. These conclusions are consistent with studies in Europe. And in May 2019, a study published in the Journal of Clinical Oncology concluded that "the incidence rate of BIA-ALCL may be higher than previously reported."

80. Despite the studies and reports demonstrating this heightened risk of BIA-ALCL, Allergan continued to sell its Recalled BIOCELL Implants.

81. In December 2018, Allergan textured breast implants lost their European certification and subsequently were suspended from the European and Brazilian markets. Allergan textured implants were banned in France in April 2019 and in Canada in May 2019.

82. In February 2019, the FDA issued a Letter to Health Care Providers across the United States warning them about the link between BIA-ALCL and textured implants.

83. In its July 24, 2019 safety communication recalling the product, the FDA announced that a total of 573 unique BIA-ALCL cases had been reported, including 33 patient deaths. Of those 573 cases, 481 patients—more than 80%—were reported to have Allergan breast implants at the time of diagnosis. And of the 13 deaths for which product identification was available, 12 occurred in patients with an Allergan breast implant at the time of their diagnosis.

84. The FDA further stated that its "analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers." It concluded that continued distribution of Allergan's BIOCELL textured implants "would likely cause serious, adverse health consequences and potentially death from BIA-ALCL."

**D. Allergan Concealed the Risks of its Recalled BIOCELL Implants**

85. Allergan is responsible for the safety of its Recalled BIOCELL Implants.

86. Allergan is responsible for timely communicating complete and accurate safety information regarding its devices, including its Recalled BIOCELL Implants, and for monitoring all reasonably available information and clinical experiences. It also has a duty to file adverse event reports with the FDA.

87. The FDA publishes adverse event reports for medical devices in its publicly searchable database entitled Manufacturer and User Facility Device Experience ("MAUDE"), which is updated monthly.

88. Consumers, patients, and medical personnel rely on the timely and accurate disclosure of this safety-related information in their decision-making. Researchers, including those studying the connection between breast implants and cancer or other serious health issues, also rely upon the MAUDE database in their studies.

89. Allergan failed to timely, adequately, and appropriately submit adverse event reports and otherwise appropriately disclose complete and accurate safety information regarding its Recalled BIOCELL Implants.

90. Instead of accurately reporting adverse events individually each time an injury occurred, Allergan sought to "bury evidence of ruptures and other injuries

by reporting them as routine events that did not require public disclosure." It did this by filing Alternative Summary reports ("ASRs"), which bypass MAUDE.

91. ASRs were originally developed to reduce paperwork. The program allowed Allergan to report hundreds of thousands of adverse event reports together on less-detailed quarterly spreadsheets. In doing so, Allergan also avoided public disclosure, because ASRs were generally unavailable to the public.

92. The ASR program was never intended to permit bulk filing of severe or unexpected injuries that necessitated remedial action—such reports must be disclosed individually via MAUDE. Nonetheless, Allergan buried serious events in non-public ASR reports, including a possible case of BIA-ALCL. In doing so, it misled medical professionals, patients, the public, and researchers regarding the type and severity of problem associated with its breast implants, manipulating patients' decision-making process and exposing them to harm.

93. The FDA discontinued use of ASRs in 2017. Lest there was any doubt that serious breast implant adverse events had been buried in ASRs, following the discontinuation of the ASR program, the number of reported breast implant adverse events dramatically increased—from 200 a year to 4,567 in 2017 and 8,242 in the first half of 2018.

94. The FDA has now acknowledged that, until recently, there was a "transparency issue" with the injury reports it had been accepting. It also stated that

the surge in reports following the discontinuation of its ASR program reflected the change in its requirements, rather than "a new public health issue."

95. Upon information and belief, Allergan also did not report adverse events from its required post-market approval studies that would have suggested that the Recalled BIOCELL Implants have caused or contributed to deaths or serious bodily injury.

96. Beginning in at least 2006, Allergen possessed information and evidence demonstrating that its Recalled BIOCELL Implants posed a significant risk of BIA-ALCL.

97. Allergan failed to comply with the conditions of its PMAs and violated state and federal law by failing to properly investigate, identify, disclose, warn of, and report the risks of and adverse events associated with its Recalled BIOCELL Implants, including the risk of BIA-ALCL, and by continuing to sell the now-Recalled BIOCELL Implants.

98. Had Allergan complied with its obligations under state and federal law and timely, adequately, and appropriately disclosed the connection between BIOCELL breast implants and tissue expanders and BIA-ALCL, patients, including Plaintiffs and the class members, and their treating physicians would have been able to make an informed decision regarding their use of BIOCELL implants.

99. Applicable state law does not impose duties or requirements materially different from those imposed by federal law, as described herein.

## CLASS ALLEGATIONS

100. Plaintiffs bring this action in their individual capacity and on behalf of the following class ("class") pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Nationwide Class:** All individuals in the United States who, for personal use, implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

101. Excluded from the Class are Defendants and any of their affiliates, parents, subsidiaries, officers, and directors; any entity in which Defendants have a controlling interest; all persons who make a timely election to be excluded from the class; governmental entities; and all judges assigned to hear any aspect of this litigation, including their immediate family members.

102. Plaintiffs reserve the right to modify or amend the class definitions, including the addition of one or more subclasses, after having the opportunity to conduct discovery.

103. Numerosity: The FDA has estimated that hundreds of thousands of individuals have been implanted with the Recalled BIOCELL Implants. The September 11, 2019 Class I Recall Notice indicates that there are a total 4,026,287 breast implants and tissue expanders "in commerce." The members of the Class are so numerous that joinder is impractical.

104. Typicality: Plaintiffs' claims are typical of the claims of the class in that Plaintiffs, like all class members, were implanted with the Recalled BIOCELL Implants and face an increased risk of BIA-ALCL. Plaintiffs and the class members were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of herself and the Class Members.

105. Adequacy: Plaintiffs will fairly and adequately protect the interest of the class. Plaintiffs' interests and the interests of all other members of the class are identical, and Plaintiffs are cognizant of her duty and responsibility to each respective class. Further, the interests of the Nationwide Class are not conflicting or divergent but, rather, are common. Accordingly, Plaintiffs can fairly and adequately represent the interests of the Class. Moreover, Plaintiffs' counsel are competent and experienced in litigating class actions, including litigation of this kind. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the Class Members' interests.

106. Commonality and Predominance: There are numerous questions of law and fact common to the class, and these common questions predominate over any issues affecting only individual class members. Questions common to the class include, but are not limited to:

a. Whether the Recalled BIOCELL Implants significantly increase the risk of developing BIA-ALCL;

b. Whether Allergan knew or should have known that the Recalled BIOCELL Implants significantly increase the risk of developing BIA-ALCL:

c. Whether Allergan was negligent in selling the Recalled BIOCELL Implants;

d. Whether Allergan failed to warn consumers regarding the risks of the Recalled BIOCELL Implants;

e. Whether Allergan violated federal standards and requirements for the marketing, warning, and reporting of the Recalled BIOCELL Implants;

f. Whether Allergan breached implied warranties connected with the Recalled BIOCELL Implants;

g. Whether Plaintiffs and class members are entitled to equitable relief, including medical monitoring;

h. Whether Plaintiffs and class members are entitled to recover the costs of explantation in order to mitigate their risk of developing BIA-ALCL.

107. Superiority: a class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual Plaintiffs may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiffs and the Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendants, and thus, individual litigation to redress Defendants' wrongful conduct would be impracticable. Individual litigation by each Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

108. Injunctive and Declaratory Relief: Class certification is also appropriate under Rule 23(b)(2) because Allergan has acted and refused to act on grounds generally applicable to the class as a whole, such that final injunctive relief

is appropriate with respect to the class as a whole. Such injunctive relief includes, but is not limited to, the implementation and funding of a medical monitoring program for the Plaintiffs and the class members that is sufficient to monitor their health and to ensure the beneficial early detection of diseases, specifically BIA-ALCL, caused by exposure to Defendants' Recalled BIOCELL Implants.

109. This action is also properly maintainable under Rule 23(c)(4) in that particular issues common to the class, as described in part in paragraph 101, are most appropriately and efficiently resolved via class action, and would advance the disposition of this matter and the parties' interests therein.

**COUNT I: STRICT PRODUCTS LIABILITY- FAILURE TO WARN**

110. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

111. Defendants manufactured, distributed, and/or sold the Recalled BIOCELL Implants that were implanted in Plaintiffs and the class members.

112. Defendants had a duty to warn Plaintiff, the class members, and their physicians regarding the known and knowable dangers of and potential risks posed by its Recalled BIOCELL Implants.

113. The Recalled BIOCELL Implants had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally

accepted in the scientific and medical communities at the time of the manufacture, distribution, and/or sale of the products.

114. The potential risks, including the substantial risk of BIA-ALCL, presented a substantial danger to Plaintiffs and the class members when the BIOCELL products were used or misused an in intended or reasonably foreseeable way.

115. Ordinary consumers, including Plaintiffs and the class members, would not have recognized these potential risks, and Allergan knew this.

116. Allergan failed to adequately warn or instruct Plaintiffs, the class members, and their physicians of the potential risks, including the risk of BIA-ALCL. At the time that Plaintiffs received her implants, Allergan knew or should have known of the clear causal connection between its Recalled BIOCELL Implants and BIA-ALCL, but it did not disclose this information to Plaintiffs or her physician and did not warn of the significantly greater risk of BIA-ALCL posed by its product.

117. Allergan obtained this information from a variety of sources, including but not limited to its own clinical studies; internal data concerning adverse event reports that was subsequently submitted in ASRs, rather than publicly-available MDRs; published reports and case studies; literature concerning the safety and efficacy of its Recalled BIOCELL Implants; FDA and foreign regulatory communications; and complaints from patients and/or healthcare providers.

118. Allergan then attempted to conceal these true facts by, *inter alia,* failing to report all adverse events to the FDA, improperly reporting certain adverse events via ADRs, which are not publicly available; and failing to include the necessary information in its DFUs, patient labeling.

119. It was foreseeable to Allergan that its failure to provide sufficient instructions and/or warnings, and its failure to timely, adequately, and appropriately report required adverse event information to the FDA, would cause Plaintiffs and the class members irreparable harm, including the increased risk of developing BIA-ALCL. Allergan knew that patients and their physicians, including Plaintiffs and the class members, relied upon its labeling and adverse event disclosures.

120. If Plaintiffs and her physician had been provided with the appropriate information and warnings regarding the causal connection between Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants and would not be at an increased risk of developing BIA-ALCL.

121. Allergan's breach of its duty to warn was a substantial factor in and proximately caused Plaintiffs and the class members injury and damages, including surgical costs for removal of the products and/or ongoing medical monitoring, including invasive diagnostic procedures and other expenses.

## COUNT II: NEGLIGENCE

122. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

123. Allergan has a continuing duty to monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety. Allergan also has a continuing duty to provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants.

124. Allergan breached these duties by, *inter alia,* failing to (a) comply with applicable reporting and monitoring requirements, (b) failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiff, the class members, and their physicians, (c) failing to warn Plaintiff, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL; and (d) continuing to manufacture, distribute and/or sell the BIOCELL products notwithstanding these facts.

125. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

126. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between BIOCELL implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants and would not be at an increased risk of developing BIA-ALCL.

127. Allergan's breaches were a substantial factor in and proximately caused Plaintiffs and the class members to be at increased risk for developing BIA-ALCL and in need of ongoing medical monitoring.

**COUNT III: NEGLIGENT RECALL**

128. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

129. Despite decades of knowledge that its Recalled BIOCELL Implants pose a significantly increased risk of BIA-ALCL, Allergan continued to sell the products and failed to issue a recall. A reasonable manufacturer, distributor, and/or seller would have recalled the product under the same or similar circumstances.

130. Only when the FDA urged Allergan to recall its Recalled BIOCELL Implants on July 24, 2019 did Allergan do so. In issuing a voluntary recall, Allergan assumed duties to Plaintiffs to exercise reasonable care in issuing and implementing the recall.

131. However, Allergan's recall fails to pay for the full costs associated with surgical removal of Plaintiffs' defective Recalled BIOCELL Implants and therefore does not adequately protect Plaintiffs from injury or risk of harm.

132. As a proximate result of Allergan's breach of duty, Plaintiffs and the class members are at increased risk for developing BIA-ALCL and are in need of ongoing medical monitoring.

**COUNT IV: FRAUDULENT CONCEALMENT**

133. Plaintiffs incorporates by reference all preceding and subsequent paragraphs.

134. Allergan had a duty to disclose to Plaintiffs and her physician the true dangers and risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL.

135. Rather than complying with its reporting, disclosure, warning, and labeling obligations, Allergan intentionally concealed and/or suppressed material information regarding the safety and efficacy of the BIOCELL products, including the fact that the products cause BIA-ALCL, as well as the availability of alternative feasible safer designs.

136. These facts were known or knowable to Allergan but were not known to or readily discoverable by Plaintiffs or the class members.

137. Allergan engaged in this fraudulent concealment and suppression with the intent to deceive Plaintiffs and the class members into purchasing its Recalled BIOCELL Implants and to induce healthcare providers, including Plaintiffs' and the class members' physicians, to use the BIOCELL products.

138. If Plaintiffs and the class members had known that Allergan's BIOCELL products posed a substantial risk of BIA-ALCL, a serious disease, they would not have elected to have the recalled products implanted.

139. Allergan's malicious and intentional concealment of material information was a substantial factor in and proximately caused Plaintiffs and the class members injury, including surgical costs for removal of the products and/or ongoing medical monitoring, including invasive diagnostic procedures and other expenses.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf all others similarly situated, request that this Court:

A. Enter an order certifying this action as a class action under Federal Rule of Civil Procedure 23(a), (b)(1), (b)(2), (b)(3), and/or (c)(4), as appropriate; appointing Plaintiffs as representatives of the class; and appointing the undersigned counsel as class counsel;

B. Award Plaintiffs and the Class members equitable relief in the form of medical monitoring, including but not limited to the costs of explantation and/or ongoing diagnostic testing;

C. Award other appropriate equitable relief;

D. Award reasonable attorneys' fees and costs, as provided for by law; and

E. Grant such other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs request a trial by jury of all issues triable as of right.

Dated: November 25, 2019

Respectfully Submitted,

By: /s/ Elizabeth A. Fegan

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